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SHIPPING BIOLOGICAL MATERIALS

Introduction

There are numerous agencies and groups that have rules and regulations for the shipment of biological materials. These regulations can be conflicting and many overlap to some degree. Some of the groups that have rules for biological materials are:

- United States Department of Transportation (DOT)
- International Air Transport Association (IATA)
- United States Postal Service (USPS)
- Centers for Disease Control and Prevention (CDC)
- United States Department of Labor, Occupational Health and Safety Administration (OSHA)
- United States Department of Agriculture (USDA)

The DOT is a United States Federal agency which regulates the transport of hazardous materials to, from, or through the United States. DOT regulations are found in part 49 of the Code of Federal Regulations (49 CFR), are enforceable by law, and can carry significant fines and other penalties for failure to comply. These regulations apply to anyone who, with respect to dangerous goods or hazardous materials:

- Offers for transport
- Transports
- Causes hazardous materials to be transported
- Loads/unloads transport vehicles or aircraft
- Determines the hazard class of a hazardous material
- Selects or fills a hazardous materials packaging
- Secures a closure on a filled or partially filled hazardous materials package
- Marks or labels a package to indicate that it contains a hazardous material
- Prepares a shipping paper
- Provides and maintains emergency response information
- Reviews or signs a shipping paper to verify compliance with the Hazardous Materials Regulations or international equivalents
- Imports a hazardous material into the United States
- Manufactures and/or tests packaging materials for dangerous goods use

Such persons are considered by DOT to be Hazmat employees.

The IATA Dangerous Goods Regulation (DGR) is the industry standard for transporting dangerous goods by air. While IATA is not a federal or international regulatory agency, in general, unless the IATA DGR is followed for the air transport of dangerous goods, air carriers will not accept the shipment. IATA does not apply to packages that are shipped exclusively by ground transportation.

Both DOT and IATA have specific training requirements for persons who package and ship certain hazardous materials. Among these hazardous materials are infectious (etiologic) agents, some clinical specimens, formaldehyde solutions, and dry ice, which is covered in this manual. Procedures for shipping other chemicals is not provided in this manual. Requirements are outlined at Guidelines and Requirements for Shipping Chemicals. If you are currently shipping hazardous
chemicals other than formaldehyde or dry ice, contact your campus EHSO immediately to verify compliance with all regulatory requirements.

The CDC regulates importation of etiologic agents in 42 CFR Part 41. The USDA regulates importation of plant pests and biological agents of livestock, poultry, and other animal diseases, and regulates the transport of cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). In each of these situations, a permit is required to import or transport these materials. For information on importing these types of materials, contact the appropriate OU Environmental Health and Safety Office (EHSO) for your campus.

The Department of Commerce regulates exports of etiologic agents. A license may be required. For information regarding export and licensing requirements, go to the Commerce Department website at http://www.bis.doc.gov/licensing/exportingbasics.htm.

If shipping overseas, the Department of Commerce and other agencies have export control limitations that should be investigated by the University Export Control Officer (405/325-5052). Some guidance may be found at http://exportcontrols.ou.edu/.

Finally, any time biological materials are shipped to another institution other than for testing or diagnosis, a Material Transfer Agreement may be needed. Contact the Office of Research Administration (OUHSC and OU-Tulsa) or the Office of Research Services (OU-Norman) to have a determination made whether one is needed.

**Operator/Carrier’s Responsibilities**

The operator/carrier is responsible for:

1. accepting a properly packaged material and properly completed shipping papers;
2. proper storage and loading of the package;
3. retention of records; and
4. operator employee training.

A carrier may open any package in its possession.

**Shipper’s Responsibilities**

Because of these multiple requirements, the shipper has several responsibilities, some of which are required by law. Only the shipper has direct knowledge of what the package contains. It is the shipper’s responsibility to:

1. be properly trained on the requirements;
2. properly classify and describe the hazardous material being shipped;
3. identify the proper shipping name(s) and UN number;
4. determine that the packaging or container is an authorized packaging;
5. properly pack the material in accordance with the packaging manufacturer’s procedures, including applying closures consistent with the manufacturer’s closure instructions;
6. properly label and mark the packaging;
7. remove or obliterate any irrelevant marking already on the package or overpack;
8. provide an emergency response telephone number of a person who is either knowledgeable of the hazardous material being shipped and has comprehensive emergency response and incident mitigation information for that material, or has immediate access to a person who possesses such knowledge and information;

9. prepare appropriate shipping papers and manifest documentation; and

10. retain a copy of the shipping paper for two years after the material is accepted by the initial carrier.

**Shipper’s Step One: Be Properly Trained on the Requirements**

DOT requires initial training for hazmat employees who prepare packages for shipment which includes general awareness/familiarization, function-specific, and safety training. In addition, Security Awareness Training is **MANDATORY** for anyone shipping Category A infectious materials. This training provides an awareness of security risks associated with hazardous materials transportation, methods designed to enhance transportation security and how to recognize and respond to possible security threats. Recurrent training is required every three years.

IATA requires similar training, but recurrent training is required every two years.

This training program will provide the general awareness and function-specific training information on preparing a package for shipment, including the proper identification, packaging, labeling, and documentation, for infectious substances, diagnostic specimens, dry ice, and formaldehyde solutions only. Should additional types of materials need to be shipped, contact your campus EHSO.

Safety training requirements are to be met by having current Hazard Communication training, current Bloodborne Pathogen training for human specimens such as human blood or human tissue, and/or Laboratory Safety training for non-clinical infectious substances.

The **mandatory** Security Awareness Training (required for shipping Category A materials but not Category B materials) is accomplished by completing a separate training module provided by DOT. This training must be performed by accessing a separate CD-ROM (contact the Oklahoma City EHSO for a copy) or completing the training at the Dangerous Goods International Training Center website at [http://dgitraining.com/pages/free-security-awareness-training.html](http://dgitraining.com/pages/free-security-awareness-training.html). This separate, but required, training module has a final test which should be completed, printed, and attached to the certificate that you will receive upon completion of this self-study training course. If you do not complete this additional module and maintain the final test results, you may have difficulty proving to a regulatory inspector that all training requirements have been met.

**Shipper’s Step Two: Properly Classify the Material**

**HAZARD CLASSIFICATION**

In both international and domestic transportation, there are nine classes of dangerous goods. Some of these classes are further divided into divisions, based on their hazard characteristics. Each of these classes have specific shipping placarding and package labeling requirements. Placards are used to represent the hazard classes of materials contained within freight containers, motor vehicles or train car. Labels communicate the same hazards for smaller containers and packages offered for transport. Examples of the placards and labels used for the various hazard classes follow.
<table>
<thead>
<tr>
<th>Class 1: Explosives</th>
<th>Class 2: Gases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division 1.1 Explosives with a mass explosion hazard</td>
<td>Division 2.1 Flammable gases</td>
</tr>
<tr>
<td>Division 1.2 Explosives with a projection hazard</td>
<td>Division 2.2 Nonflammable, non-toxic* gases</td>
</tr>
<tr>
<td>Division 1.3 Explosives with predominantly a fire hazard</td>
<td>Division 2.3 Toxic* gases</td>
</tr>
<tr>
<td>Division 1.4 Explosives with no significant blast hazard</td>
<td>* The words &quot;poison&quot; or &quot;poisonous&quot; are synonymous with the word &quot;toxic&quot;</td>
</tr>
<tr>
<td>Division 1.5 Very insensitive explosives with a mass explosion hazard</td>
<td></td>
</tr>
<tr>
<td>Division 1.6 Extremely insensitive detonating articles</td>
<td></td>
</tr>
</tbody>
</table>

| Class 3: Flammable liquids (and Combustible liquids) |
### Class 4: Flammable solids; Spontaneously combustible materials; Dangerous when wet materials/Water-reactive substances

- **Division 4.1 Flammable solids**
- **Division 4.2 Spontaneously combustible materials**
- **Division 4.3 Water-reactive substances/Dangerous when wet materials**

### Class 5: Oxidizers and Organic peroxides

- **Division 5.1 Oxidizers**
- **Division 5.2 Organic peroxides**

### Class 6: Toxic* substances and Infectious substances

* The words "poison" or "poisonous" are synonymous with the word "toxic"

### Class 7: Radioactive materials

Any material, or combination of materials, that spontaneously gives off ionizing radiation. It has a specific activity greater than 0.002 microcuries per gram.
In general, infectious substances are found in hazard class 6, division 2, a.k.a “Division 6.2.” Biological toxins may be found in Division 6.1.

Dry ice is often packaged with infectious substances and patient specimens. Dry ice falls into hazard class 9.

Formaldehyde solutions may fall into class 3, 8, or 9, depending on the concentration and other materials present. Specimens shipped in formalin solutions containing between 10-25% formaldehyde would be considered hazard class 9. Solutions containing less than 10% formaldehyde, and which contain no other hazardous material, are not regulated as a hazardous material.

DEFINITIONS

To better identify the material being shipped and ensure it is properly classified, it is important to understand the regulatory and guideline definitions of infectious substances, diagnostic specimens, and other terminology, which are presented here.

Department of Transportation (DOT)
(from 49 CFR 173.134 - Class 6, Division 6.2 - Definitions and exceptions)

Division 6.2 (infectious substance) means a material known or reasonably suspected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals.

An infectious substance must be assigned the identification number either UN 2900, Infectious substance, affecting animals, UN 2814, Infectious substances, affecting humans or UN 3373, Biological Substance, Category B, as appropriate, and must be assigned to one of the following categories:

Category A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A Category A infectious substance must be assigned to identification number UN2814 or UN2900, as appropriate. Assignment to UN 2814 or UN 2900 must be based on the known medical history or symptoms of the source patient or animal,
endemic local conditions, or professional judgement concerning the individual circumstances of the source human or animal. See the section entitled Shipper’s Step Three: Identify the Proper Shipping Name(s) and UN Numbers on page 13 for more information on UN numbers.

**Category B:** An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as “Biological substance, category B” and assigned identification number UN3373.

*Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition in human beings or animals...Unless otherwise excepted, a biological product known to reasonably expected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned the identification number UN2814 or UN2900.

*Culture* means an infectious substance containing a pathogen that is intentionally propagated. This definition does not include a human or animal patient specimen as defined below.

*Patient specimen* means human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. *Patient specimen* includes excreta, secreta, blood and its components, tissue and tissue fluid swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles).

**Exceptions** The following are not subject to the DOT requirements as Division 6.2 materials:

- A material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.
- Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic material.
- A material containing microorganisms that are non-pathogenic to humans or animals.
- A material containing pathogens that have been neutralized or inactivated such that they no longer pose a health risk.
- A material with a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include: foodstuffs; environmental samples, such as water or a sample of dust or mold; and substances that have been treated so that the pathogens have been neutralized or deactivated, such as a material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.
- A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture.
- Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular
and tissue-based products regulated under authority of the Public Health Service Act (42 U.S.C. 264–272) and/or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).

- Blood, blood plasma, and blood components collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped as a Category A or Category B infectious substance, as appropriate.

- Dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material.

- A Division 6.2 material, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

- A human or animal sample (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

Note that live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the DOT Associate Administrator for Hazardous Materials Safety.

The shipping names Diagnostic specimens and Clinical specimens are no longer permitted. Keep in mind that routine shipment of human or animal blood or tissue samples which are not known or suspected of containing a pathogen, and which are not being sent for pathogen testing, are not considered infectious materials for shipping purposes and are therefore not regulated by DOT. It is best to call these sorts of materials “patient specimens.”

International Air Transport Association (IATA)
(from 3.6.2 Division 6.2 - Infectious Substances)

3.6.2.1.1 Infectious substances are substances known to contain, or are reasonably expected to contain, pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. Note: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are contained in substances which are not infectious substances should be considered for classification in Division 6.1 and assigned to UN 3172.

Infectious substances are divided into the following categories:

Category A: An infectious substance which is transported in a form that, when exposure to it occurs (when the infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals), is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D. of the IATA regulations and include, but are not limited to, the following two lists.
**UN 2814 Infectious Substances Affecting Humans**

<table>
<thead>
<tr>
<th>Organism/Pathogen</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacillus anthracis (cultures only)</td>
<td>Highly pathogenic avian influenza virus</td>
</tr>
<tr>
<td>Brucella abortus (cultures only)</td>
<td>(cultures only)</td>
</tr>
<tr>
<td>Brucella melitensis (cultures only)</td>
<td>Japanese Encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Brucella suis (cultures only)</td>
<td>Junin virus</td>
</tr>
<tr>
<td>Burkholderia mallei - Pseudomonas mallei - Glanders (cultures only)</td>
<td>Kyasanur Forest disease virus</td>
</tr>
<tr>
<td>Burkholderia pseudomallei - Pseudomonas pseudomallei (cultures only)</td>
<td>Machupo virus</td>
</tr>
<tr>
<td>Chlamydia psittaci - avian strains (cultures only)</td>
<td>Marburg virus</td>
</tr>
<tr>
<td>Clostridium botulinum (cultures only)</td>
<td>Monkeypox virus</td>
</tr>
<tr>
<td>Coccidioides immitis (cultures only)</td>
<td>Mycobacterium tuberculosis (cultures only)</td>
</tr>
<tr>
<td>Coxiella burnetii (cultures only)</td>
<td>Poliovirus (cultures only)</td>
</tr>
<tr>
<td>Crimean-Congo hemorrhagic fever virus (cultures only)</td>
<td>Rabies virus (cultures only)</td>
</tr>
<tr>
<td>Dengue virus (cultures only)</td>
<td>Rickettsia prowazekii (cultures only)</td>
</tr>
<tr>
<td>Eastern equine encephalitis virus (cultures only)</td>
<td>Rickettsia rickettsii (cultures only)</td>
</tr>
<tr>
<td>Escherichia coli, verotoxigenic (cultures only)</td>
<td>Rift Valley fever virus (cultures only)</td>
</tr>
<tr>
<td>Ebola virus (cultures only)</td>
<td>Russian spring-summer encephalitis virus</td>
</tr>
<tr>
<td>Flexal virus</td>
<td>Sabia virus</td>
</tr>
<tr>
<td>Francisella tularensis (cultures only)</td>
<td>Shigella dysenteriae type 1 (cultures only)</td>
</tr>
<tr>
<td>Guanarito virus</td>
<td>Tick-borne encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Hantaan virus</td>
<td>Variola virus</td>
</tr>
<tr>
<td>Hantavirus causing hemorrhagic fever with renal syndrome</td>
<td>Venezuelan equine encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Hendra virus</td>
<td>West Nile virus (cultures only)</td>
</tr>
<tr>
<td>Hepatitis B virus (cultures only)</td>
<td>Yellow fever virus (cultures only)</td>
</tr>
<tr>
<td>Herpes B virus (cultures only)</td>
<td>Yersinia pestis (cultures only)</td>
</tr>
<tr>
<td>Human immunodeficiency virus (cultures only)</td>
<td></td>
</tr>
</tbody>
</table>

**UN 2900 Infectious Substances Affecting Animals**

<table>
<thead>
<tr>
<th>Organism/Pathogen</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>African swine fever virus (cultures only)</td>
<td>Peste des petits ruminants virus (cultures only)</td>
</tr>
<tr>
<td>Avian paramyxovirus Type 1 - Velogenic</td>
<td>Rinderpest virus (cultures only)</td>
</tr>
<tr>
<td>Classical swine fever virus (cultures only)</td>
<td>Sheep-pox virus (cultures only)</td>
</tr>
<tr>
<td>Foot and mouth disease virus (cultures only)</td>
<td>Goatpox virus (cultures only)</td>
</tr>
<tr>
<td>Lumpy skin disease virus (cultures only)</td>
<td>Swine vesicular disease virus (cultures only)</td>
</tr>
<tr>
<td>Newcastle disease virus (cultures only)</td>
<td>Vesicular stomatitis virus (cultures only)</td>
</tr>
<tr>
<td>Mycoplasma mycoides - Contagious bovine pleuropneumonia (cultures only)</td>
<td></td>
</tr>
</tbody>
</table>

Infectious substances meeting these criteria which cause disease in humans or both in humans and in animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900. Assignment to UN2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individuals circumstances of the source human or animal.

**NOTE:** The previous lists for Category A materials are not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the list but which meet the same criteria must also be considered Category A. If there is doubt as to whether or not a substance meets the criteria, it should be included in Category A.

**Category B:** An infectious substance which does not meet the criteria for inclusion in Category A.
Infectious substances in Category B should be assigned to UN 3373. The proper shipping name of UN3373 is “Biological substance, category B”. As of January 1, 2007 the use of the shipping names Diagnostic specimens and Clinical specimens is no longer permitted.

3.6.2.1.3 Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in 3.6.2.1.4.

3.6.2.1.4 Patient specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, diseases treatment and prevention.

3.6.2.1.2 Biological Products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental, or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

For IATA purposes, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to the IATA regulations.

(b) those which do not meet the criteria of paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN 2814, UN2900, or UN3373, as appropriate.

Genetically modified organisms and microorganisms which do not meet the definition of infectious substances but which are capable of altering animals, plants, or microbiological substances in a way which is not normally the result of natural reproduction are considered by IATA to be Class 9 and are assigned UN 3245, Genetically modified micro-organisms. DOT does not have a corresponding definition or UN number for genetically modified organisms/microorganisms. For assistance with shipping these items, contact the EHSO.

The following are not subject to the IATA regulations unless they meet the criteria for inclusion in another class:

- Substances which do not contain infectious substances
- Substances containing microorganisms which are non-pathogenic to human or animals
- Substances which are unlikely to cause disease in humans or animals
- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk
- Environmental samples which are not considered to pose a significant risk of infection

A live animal which has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be transported under terms and conditions approved by the appropriate national authority.
NOTE: These shipping definitions are completely independent from those provided by the OSHA Bloodborne Pathogen regulation in which ALL human blood and certain body fluids must be presumed to be infectious, regardless of the source. For shipping purposes, only human blood and body fluids that are known or reasonably expected to contain pathogens are to be classified as Division 6.2 infectious substances. All other human blood or tissue samples are not regulated by DOT or IATA for shipping purposes.

Examples

Examples of materials to be considered Category A infectious substances:

- Cultures (laboratory stocks) of pathogens (microorganisms capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals) such as Coxiella burnetii (UN 2814) or Vesicular stomatitis virus (UN 2900)
- Human blood or tissue known to contain or suspected of containing Ebola virus (UN 2814)

Examples of materials which may be considered Category B infectious substances/ Biological substance, Category B (UN 3373):

- Cultures of Bacillus cereus
- Human sputum being sent for confirmatory TB testing
- Human blood or tissue known to contain or suspected of containing HIV, or being sent for HIV testing
- Animal blood or tissue known to contain or suspected of containing Vesticular stomatitis virus
- Animal feces being sent for testing for the presence of Lysteria monocytogenes

Examples of materials which are currently not regulated as infectious substances or diagnostic specimens, but are considered “patient specimens”:

- Human blood or urine from a healthy person being sent for cholesterol, pregnancy, or other non-pathogenic testing
- Human tissue being sent for pathological evaluation (from a person not known to have an infectious disease)
- Animal tissue with a low risk probability of being infectious being sent for research purposes other than diagnosis of infectious agents

The University of New Hampshire and the University of Illinois have developed a Classification Guide in flow chart format that is very useful in helping determine the classification, and therefore shipping requirements for individual shipments. This guide is available at https://www.drs.illinois.edu/Programs/IntroductiontoShipping.

Biological Toxins

For DOT purposes, poisonous material (Division 6.1) means a material, other than a gas, which is known to be so toxic to humans as to afford a hazard to health during transportation, or which, in the absence of adequate data on human toxicity:

1. Is presumed to be toxic to humans because it falls within any one of the following categories when tested on laboratory animals (whenever possible, animal test data that
has been reported in the chemical literature should be used):

(i) Oral Toxicity. A liquid or solid with an LD$_{50}$ for acute oral toxicity of not more than 300 mg/kg.

(ii) Dermal Toxicity. A material with an LD$_{50}$ for acute dermal toxicity of not more than 1000 mg/kg.

(iii) Inhalation Toxicity.

   (A) A dust or mist with an LC$_{50}$ for acute toxicity on inhalation of not more than 4 mg/L; or

   (B) A material with a saturated vapor concentration in air at 20 °C (68 °F) greater than or equal to one-fifth of the LC$_{50}$ for acute toxicity on inhalation of vapors and with an LC$_{50}$ for acute toxicity on inhalation of vapors of not more than 5000 mL/m$^3$, or

(2) Is an irritating material, with properties similar to tear gas, which causes extreme irritation, especially in confined spaces.

For the purposes of these requirements:

- LD$_{50}$ (median lethal dose) for acute oral toxicity is the statistically derived single dose of a substance that can be expected to cause death within 14 days in 50% of young adult albino rats when administered by the oral route. The LD$_{50}$ value is expressed in terms of mass of test substance per mass of test animal (mg/kg).

- LD$_{50}$ for acute dermal toxicity means that dose of the material which, administered by continuous contact for 24 hours with the shaved intact skin (avoiding abrading) of an albino rabbit, causes death within 14 days in half of the animals tested. The number of animals tested must be sufficient to give statistically valid results and be in conformity with good pharmacological practices. The result is expressed in mg/kg body mass.

- LC$_{50}$ for acute toxicity on inhalation means that concentration of vapor, mist, or dust which, administered by continuous inhalation for one hour to both male and female young adult albino rats, causes death within 14 days in half of the animals tested. If the material is administered to the animals as a dust or mist, more than 90 percent of the particles available for inhalation in the test must have a diameter of 10 microns or less if it is reasonably foreseeable that such concentrations could be encountered by a human during transport. The result is expressed in mg/L of air for dusts and mists or in mL/m$^3$ of air (parts per million) for vapors.

DOT and IATA have slightly different criteria for categorizing the packing groups for Division 6.1 biological toxins.

**DOT 173.133 Packing Groups**

<table>
<thead>
<tr>
<th>Packing Group</th>
<th>Oral Toxicity LD$_{50}$ (mg/kg)</th>
<th>Dermal Toxicity LD$_{50}$ (mg/kg)</th>
<th>Inhalation Toxicity by Dust and Mists LC$_{50}$ (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>≤ 5.0</td>
<td>≤ 50</td>
<td>≤ 0.2</td>
</tr>
<tr>
<td>II</td>
<td>&gt; 5 and ≤ 50</td>
<td>&gt; 50 and ≤ 200</td>
<td>&gt; 0.2 and ≤ 2.0</td>
</tr>
<tr>
<td>III</td>
<td>&gt; 50 and ≤ 300</td>
<td>&gt; 200 and ≤ 1000</td>
<td>&gt; 2.0 and ≤ 4.0</td>
</tr>
</tbody>
</table>
**IATA Table 3.6.A Oral, Dermal and Dust/Mist Inhalation Hazards Division 6.1 Packing Groups**

<table>
<thead>
<tr>
<th>Packing Group</th>
<th>Oral Toxicity LD$_{50}$ (mg/kg)</th>
<th>Dermal Toxicity LD$_{50}$ (mg/kg)</th>
<th>Inhalation Toxicity by Dust and Mists LC$_{50}$ (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>≤ 5</td>
<td>≤ 40</td>
<td>≤0.5</td>
</tr>
<tr>
<td>II</td>
<td>&gt; 5 but ≤ 50</td>
<td>&gt; 40 but ≤ 200</td>
<td>&gt; 0.5 but ≤ 2</td>
</tr>
<tr>
<td>III</td>
<td>Solids: &gt; 50 but ≤ 200</td>
<td>&gt; 200 but ≤1000</td>
<td>&gt; 2 but ≤10</td>
</tr>
<tr>
<td></td>
<td>Liquids: &gt; 50 but ≤ 500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In addition, if the material to be shipped falls under OSHA’s definition of a hazardous material, using the definition of acutely toxic found at 29 CFR 1910.1200 Appendix A, the material must be labeled and a safety data sheet provided for the material. An acutely toxic material, according to OSHA, is any material with the following characteristics:

<table>
<thead>
<tr>
<th>Exposure route</th>
<th>LD$<em>{50}$/LC$</em>{50}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>≤ 2000mg/kg bodyweight</td>
</tr>
<tr>
<td>Dermal</td>
<td>≤ 2000mg/kg bodyweight</td>
</tr>
<tr>
<td>Inhalation - Gases</td>
<td>≤ 20000 ppmV</td>
</tr>
<tr>
<td>Inhalation - Vapors</td>
<td>≤ 20.0mg/l</td>
</tr>
<tr>
<td>Inhalation – Dusts and Mists</td>
<td>≤ 5.0mg/l</td>
</tr>
</tbody>
</table>

Contact the EHSO for assistance whenever a biological toxin is needing to be shipped.

**Shipper's Step Three: Identify the Proper Shipping Name(s) and UN Numbers**

When offering dangerous goods for transportation, the proper shipping name and associated United Nation (UN) number must be identified for each material shipped. This is done by referencing the DOT Hazardous Materials Table and/or tables in the IATA DGR. Appropriate proper shipping names and UN numbers have been extracted from these tables and are provided in the following summary table.

<table>
<thead>
<tr>
<th>Proper Shipping Name</th>
<th>UN Number</th>
<th>Hazard Class</th>
<th>Packing Group (PG)</th>
<th>Packing Instruction (PI)</th>
<th>Max. Net qty./pkg. for Passenger Aircraft</th>
<th>Max. Net qty./pkg. for Cargo Aircraft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious substance, affecting animals (technical name)</td>
<td>UN 2900</td>
<td>6.2</td>
<td>-</td>
<td>620</td>
<td>50 mL or 50 g</td>
<td>4 L or 4 kg</td>
</tr>
<tr>
<td>Infectious substances, affecting humans (technical name)</td>
<td>UN 2814</td>
<td>6.2</td>
<td>-</td>
<td>620</td>
<td>50 mL or 50 g</td>
<td>4 L or 4 kg</td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>UN Number</td>
<td>Hazard Class</td>
<td>Packing Group (PG)</td>
<td>Packing Instruction (PI)</td>
<td>Max. Net qty./pkg. for Passenger Aircraft</td>
<td>Max. Net qty./pkg. for Cargo Aircraft</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------</td>
<td>--------------</td>
<td>-------------------</td>
<td>-------------------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Biological substance, category B</td>
<td>UN 3373</td>
<td>-</td>
<td>-</td>
<td>650</td>
<td>4 L or 4 kg</td>
<td>4 L or 4 kg</td>
</tr>
<tr>
<td>Genetically modified micro-organisms</td>
<td>UN 3245 (IATA only)</td>
<td>9</td>
<td>-</td>
<td>913</td>
<td>No Limit</td>
<td>No Limit</td>
</tr>
<tr>
<td>Toxins, extracted from living sources, liquid, n.o.s. (toxin name)</td>
<td>UN 3172</td>
<td>6.1</td>
<td>I II III</td>
<td>603¹/604² 609¹/611² 611¹/618²</td>
<td>1 L 5 L 60 L</td>
<td>30 L 60 L 220 L</td>
</tr>
<tr>
<td>Toxins, extracted from living sources, solid, n.o.s. (toxin name)</td>
<td>UN 3462</td>
<td>6.1</td>
<td>I II III</td>
<td>606¹/607² 613¹/615² 619¹/619²</td>
<td>5 kg 25 kg 100 kg</td>
<td>50 kg 100 kg 200 kg</td>
</tr>
<tr>
<td>Carbon dioxide, solid (dry ice)</td>
<td>UN 1845</td>
<td>9</td>
<td>-</td>
<td>954</td>
<td>200 kg</td>
<td>200 kg</td>
</tr>
<tr>
<td>Formaldehyde solutions, flammable³</td>
<td>UN 1198</td>
<td>3 (label code 3,8)</td>
<td>III</td>
<td>309</td>
<td>5 L</td>
<td>60 L</td>
</tr>
<tr>
<td>Formaldehyde solutions, (with not less than 25% formaldehyde⁴)</td>
<td>UN 2209</td>
<td>8</td>
<td>III</td>
<td>818</td>
<td>5 L</td>
<td>60 L</td>
</tr>
<tr>
<td>Aviation regulated liquid, n.o.s. (formaldehyde⁵)</td>
<td>UN 3334</td>
<td>9</td>
<td>-</td>
<td>906</td>
<td>100 L</td>
<td>220 L</td>
</tr>
</tbody>
</table>

¹Passenger  
²Cargo  
³37% Formaldehyde  
⁴25-36% Formaldehyde (flash point >141°F)  
⁵10-24.9% Formaldehyde, air only

Category A infectious substances meeting the definition of Class 6.2 which cause disease in humans or both in humans and animals should be assigned to UN 2814. Category A infectious substances which cause disease only in animals should be assigned to UN 2900. Assignment to UN 2814 or UN 2900 should be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Some of the above proper shipping names require that one or more technical name(s) of the hazardous material be entered in parentheses. A recognized technical or scientific name is one that is listed in scientific and technical handbooks, texts and journals. These are to be indicated in parentheses, immediately after the listed proper shipping name.

Example: Infectious substances, affecting humans (HIV)

Note: If the substance is capable of affecting both humans and animals, the proper shipping name is always “Infectious substances, affecting humans.”

Example: Infectious substances, affecting humans (Bacillus anthracis)

After the shipping name column is a column with assigned UN numbers. These are four-digit
numbers used world-wide in international commerce and transportation to uniquely identify hazardous chemicals or classes of hazardous materials.

There is also a column in the table indicating “Packing Group.” Packing groups indicate the level or degree of the hazard within some hazard classes and divisions and will determine the type of package in which the material can be shipped. Packing groups are used for toxin and chemicals, but not infectious substances. There are three potential packing groups, as follows:

- Packing Group I - Great Danger
- Packing Group II – Medium Danger
- Packing Group III – Minor Danger

Roman numerals must be used to denote packing groups if used, e.g., “Packing Group II.” On shipping papers, it is common and acceptable to show this as “PG II” or just “II.” IATA and DOT have removed the packing group III information for dry ice in their hazardous materials table, so this no longer is required on the shipper’s declaration for dry ice.

Shipper’s Step Four: Check with the Shipping Carrier for Limitations/Specifications

IATA no longer requires advance arrangements to be made between the shipper and the receiver, but it is important to check that the shipping vendor/carrier handles the classification type of your package (for example, UPS does not accept infectious substance shipments). Some etiologic agents listed in 42 CFR 72.3(f) must be shipped by registered mail or an equivalent system that provides notification of a receipt to the sender. If shipping materials listed in 42 CFR 72.3(f) and notice of delivery is not received by the sender within 5 days following anticipated delivery of the package, the sender is required to notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 [telephone (404) 633-5313].

Individual companies may have some carrier-specific requirements. Examples of some specifications/limitations of various shipping services are:

**Federal Express**


- Division 6.2, items classed as Risk Group 4 by the World Health Organization (WHO) or select agents will not be accepted for carriage.
- Handwritten Shipper’s Declarations will not be accepted. FedEx Express requires all Shipper’s Declarations for Dangerous Goods Forms to be prepared using approved software that incorporates dangerous goods compliance edit checks. Other on-line or in-house forms are no longer approved. Software options to meet this requirement include:
  - FedEx-approved vendor software applications – contact FedEx for the current list of approved vendors, or
- Always be sure to check with your Tier 1 or other computer support before installing any software.

- UPS does not accept/ship packages marked or labeled as Category A infectious substances.
- Category B infectious substances must be shipped in triple packaging. The UPS Laboratory Pak is designed for Next Day Air shipping and may serve as a watertight over wrap for the inner packaging. See UPS-Shipping Infectious and Biological.
- Patient specimens for which there is minimal likelihood that pathogens are present may be shipped if they are packed according to IATA triple packaging guidelines and are marked with the words "Exempt Human Specimens" or "Exempt Animal Specimens".

DHL

United States Postal Service (USPS)
Additional information is available at http://pe.usps.com/text/pub52/pub52c3_023.htm#ep925025 and http://pe.usps.com/text/pub52/pub52c3_023.htm#ep925305.

- Materials containing Category A infectious substances may not be shipped by the United States Postal Service.
- A material that is classified as a Category B infectious substance must be triple packaged, meeting the packaging requirements in 49 CFR 173.199, and sent as First Class Mail, Priority Mail, or Express Mail. The outer packaging must show the name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or of someone who has immediate access to the person with such knowledge and information.
- Exempt human and animal specimens (human or animal samples including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts transported for routine testing not related to the diagnosis of an infectious disease) are mailable as Priority Mail Express, Priority Mail, First-Class Mail, First-Class Package Service, Parcel Select, or Standard Post. Exempt human or animal specimens are not subject to regulation as hazardous materials but when presented for mailing must be triple packaged in leakproof (for liquids) or siftproof (for solids) primary receptacles. Additional requirement for exempt human and animal specimens are located at http://pe.usps.com/text/pub52/pub52c3_023.htm#ep925305.
- Dry ice (carbon dioxide, solid) is prohibited in international mail but permitted in the domestic mail via air or surface transportation if packed in containers that permit the release of carbon dioxide gas. A mailpiece containing dry ice for air transport may not contain more than 5 pounds of dry ice. The amount of dry ice per mailpiece for surface transport may exceed 5 pounds, however, the address side of each mailpiece must be clearly marked “Surface Only” or “Surface Mail Only.”

Shipper’s Step Five: Select the Proper Packaging Material and Properly Pack the Material

The type of package material and proper packing procedures will depend on the type of material
that is being sent and the method by which it is sent.

DIVISION 6.2 CATEGORY A INFECTIOUS SUBSTANCES

IATA, and DOT rules are similar for airborne shipments of infectious materials. Packaging must meet testing requirements (such as drop and pressure testing) and conform with United Nations Performance Orientation Packaging (UN/POP) markings for infectious substances. A sample of UN/POP packaging for Division 6.2 items (infectious substances) is given here.

![Sample UN Package Certification Mark]

- **UN** = United Nations Symbol
- **4** = A number indicating the type of packaging - in this case, a “box”
- **G** = A letter indicating the type of packaging material - in this case, “fibreboard”
- **CLASS 6.2** = The hazardous materials classification for which the package is designed - in this case - “Class 6.2, Infectious Substances”
- **06** = The last two digits of the year of manufacture of the package
- **USA** = The country of manufacture
- **0000** = Symbol for the test facility and/or manufacturer’s code

According to the DOT and IATA requirements, Division 6.2 packaging is a triple package consisting of the following components:

- A watertight primary receptacle.
- A watertight secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be wrapped individually to prevent contact between them.
- A rigid outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure at least 100 mm (3.9 inches DOT/4 inches IATA) at its smallest overall external dimension.
- For “other than solid” (i.e, liquid) infectious substances, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.
- An itemized list of contents enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in category A and assignment to UN2814 or UN2900, the words “Suspected Category A Infectious Substance” must be shown in parentheses following the proper shipping name on the itemized list of contents inside the outer packaging.
The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) and temperatures in the range of -40 °C to +55 °C (-40 °F to +131 °F).

An example of appropriate triple packaging for Category A infectious substances is shown here.

This packaging is also described in IATA Packing Instruction 620, which is to be used for all air shipments of Division 6.2 Category A infectious substances. A copy of IATA Packing Instruction 620 is found at [http://www.slh.wisc.edu/wp-content/uploads/2014/10/IATA-Packing-Instructions-620.pdf](http://www.slh.wisc.edu/wp-content/uploads/2014/10/IATA-Packing-Instructions-620.pdf).

Because DOT requires that shippers properly pack the material in accordance with the packaging manufacturer's procedures, including applying closures consistent with the manufacturer's closure instructions, it is strongly recommended that the packing and closure procedures provided by the manufacturer/vendor be maintained by the department.

Additional DOT and IATA requirements for packaging certain infectious substances are as follows.

- **Infectious substances shipped at ambient temperatures or higher** - Authorized primary receptacles are those made of glass, metal, or plastic. Positive means of ensuring a leakproof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape, paraffin sealing tape, or manufactured locking closure. Lyophilized substances may also be transported in primary receptacles that are flame-sealed with glass ampules or rubber-stoppered glass vials fitted with metal seals.

- **Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice)** - Ice or...
dry ice must be placed around the secondary packagings or in an overpack with one or more complete packages. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were lost. Also see the section on “Dry Ice,” page 20.

Category A Infectious substances shipped in liquid nitrogen - The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were to be lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks (also called "dry shippers") vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the Department of Transportation Associate Administrator for Hazardous Materials Safety.

CATEGORY B INFECTIOUS SUBSTANCES

According to IATA and DOT, Category B infectious substances must also be packaged in triple packaging, consisting of (a) primary receptacle(s), a secondary packaging, and a rigid outer packaging which meet the following requirements:

• Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them.

• Secondary packagings must be secured in outer packagings with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

• If liquid, the primary receptacle must be leak-proof, and absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacle(s). Secondary packaging must be leakproof.

• For shipments by aircraft, the maximum liquid quantity contained in each primary receptacle, including any material used to stabilize or prevent degradation of the sample, may not exceed 1 liter. The maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples, may not exceed 4 L (1 gallon). This outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

• For liquid shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

• Solid substances must be packaged in primary receptacle(s) and secondary packaging(s) that are siftproof. Except for packages containing body parts, organs, or
whole bodies, for shipment by aircraft, the outer packaging may not contain more than 4 kg (8.8 pounds) capacity, including any material used to stabilize or prevent degradation of the samples. This outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

- The completed package must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

- The completed package must be capable of successfully passing a drop test at a drop height of at least 1.2 meters (3.9 feet). Because the package is not marked with UN specifications like those meeting the Class 6.2 requirements, it is strongly suggested that each department maintain the certification report provided by the vendor of the package which verifies that the package meets these requirements. If a UN Class 6.2 package is used (these packages meet the drop test requirement), be sure to mark out the UN 6.2 marking.

This packaging is also described in **IATA Packing Instruction 650**, which is to be used for all air shipments of biological substances, category B, which may be found at [http://www.iata.org/whatwedo/cargo/dgr/Documents/packing-instruction-650-DGR56-en.pdf](http://www.iata.org/whatwedo/cargo/dgr/Documents/packing-instruction-650-DGR56-en.pdf).

An appropriate triple package for Category B infectious substances is shown here.

Because DOT requires that shippers properly pack the material in accordance with the packaging manufacturer’s procedures, including applying closures consistent with the manufacturer’s closure instructions, it is strongly recommended that the packing and closure procedures provided by the manufacturer/vendor be maintained by the department.

**DRY ICE**

Dry ice (carbon dioxide, solid), if used, must be placed outside the secondary packagings or in an
overpack with one or more complete packages. Interior supports must be provided to secure the secondary package in the original position after the dry ice has dissipated and the outside packaging must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were lost.

Dry ice is not regulated by the DOT for ground transportation but is regulated by air. DOT and IATA require that prior arrangements be made between the shipper and the carrier for each shipment to ensure that ventilation safety procedures are followed.

The United States Postal Service (USPS) has special restrictions on dry ice:

- It is prohibited in international mail.
- There is a quantity limit of 5 pounds of dry ice in each package for air transport.
- For ground transport, the amount may exceed 5 pounds, however the package must indicate “Surface Mail Only.”

The packaging requirements for dry ice are also described in IATA Packing Instruction 954, which may be found at http://ehs.columbia.edu/IATAPackingInstruction954.pdf.

PATIENT SPECIMENS

Patient specimens for which there is minimal likelihood that pathogens are present are not subject to the IATA or DOT regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate. If shipped by air, IATA wants packaging of these materials to meet the following conditions:

- The packaging must consist of three components:
  1. a leak-proof primary receptacle(s);
  2. a leak-proof secondary packaging; and
  3. an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm;
- For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;
- When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

**Note:** In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.
FORMALDEHYDE/FORMALIN

Patient specimens in formaldehyde/formalin solutions should be packed in packaging that has undergone a leak-proofness test, a pressure test, and a drop test. Have the vendor providing the packaging show proof that it meets IATA requirements for shipping liquids.

OVERPACKS

An overpack may be used to combine several triple packages into one large package. If dry ice is to be used, the triple package(s) and dry ice can be enclosed in a styrofoam box with a sturdy cardboard outer cover. These final layers of styrofoam and cardboard are called the "overpack" (many shipping companies are not accepting just styrofoam boxes as the final outer layer, but some may.) For cooling purposes, IATA allows an overpack to be used to contain the dry ice, provided that the overpack meets the requirements of Packing Instruction 954.

QUANTITY LIMITATIONS

The table on page 13 identifies passenger and cargo quantity limitations. In general, to ship an infectious substance or diagnostic specimen by passenger airline or the United States Postal Service, the total amount in any triple package that can be transported cannot exceed 50 mL or 50 grams. When shipped by cargo airline, the total quantity per triple package cannot exceed 4 liters or 4 kg, and the package must have a cargo only label (see next section).

Shipper’s Step Six: Properly Mark and Label the Package

Marking and labeling requirements are based on the type of material being shipped. For all classes of substances, the shipper’s and recipient’s addresses are required on outer packaging.

IATA requires all packages containing infectious substances to be marked durably and legibly on the outside of the package with the NAME and TELEPHONE NUMBER OF A PERSON RESPONSIBLE. For those infectious substances that are assigned to UN 3373 Category B infectious substances), the name and telephone number of a responsible person need not be on the outer package, rather, the information, along with the person’s address, may either be included on the air waybill or on the package.

Labels on the outer packaging must be placed on the same side of the package as the proper shipping name. The outer packaging must be of sufficient size to accommodate all labels placed on a single surface and labels must not overlap.

For category A infectious substances, in addition to the UN/POP marking (see page 17), each outer package of must have a DOT Hazard Class 6 Label (see below). IMPORTANT: Effective October, 2005, the DOT Class 6 label MUST NOT have the CDC’s 800 telephone number.

Hazard Class 6.2 Label (left =prior to October 1, 2014, right = after October 1, 2014)
For patient specimens and Class B Infectious substances, the DOT Hazard Class 6.2 label is NOT to be used.

If dry ice is used, a Hazard Class 9 label is also required. Effective October 1, 2014, the Hazard Class 9 label will not have the line separating the top and bottom, but DOT has stated in a letter of interpretation that either may be used after October 1, 2014.

Hazard Class 9 Label (left = prior to October 1, 2014, right = after October 1, 2014)

The proper shipping name for all hazardous materials and the UN shipping number should be indicated. NEW: On the package, the technical name in parenthesis should NOT be marked on the outer package, however, it is mandatory on the Shipping Papers.

As of January 1, 2014, mandatory size for UN number and letters under IATA are as indicated on the following table. The UN number and letters MUST be at least the size specified below whereas other package markings SHOULD be that minimum size.

<table>
<thead>
<tr>
<th>Size of Package</th>
<th>Size of Text</th>
<th>Font Size (Arial)</th>
<th>Font Size (Times New Roman)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larger than 30 kg or 30 L</td>
<td>12 mm</td>
<td>48</td>
<td>52</td>
</tr>
<tr>
<td>Not more than 30 kg or 30 L</td>
<td>6 mm</td>
<td>25</td>
<td>26</td>
</tr>
<tr>
<td>Not more than 5 kg or 5 L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cylinders not more than 60 L water capacity (IMDG only)</td>
<td>6 mm</td>
<td>25</td>
<td>26</td>
</tr>
</tbody>
</table>

For dry ice, the net quantity must be indicated.

**Carbon dioxide, solid**
(Dry ice)
**UN1845**
_____ kg.
For category A infectious substances, net quantity is optional.

**Infectious substances, affecting humans**  
**UN2814**  
____ mL (optional)


Packages containing Category B infectious substances require a mark in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 2 inches, the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high.

The proper shipping name “Biological substance, category B” in letters at least 6mm high must be marked on the package adjacent to the diamond-shaped mark. The net quantity is not required to be marked on the outside of the package.

For packages containing liquid infectious substances in primary receptacles exceeding 50 ml, two package orientation labels must be affixed. DOT states that these arrows must be placed on two opposite vertical sides of the package with the arrows pointing in the appropriate direction. A rectangular border around the arrows is optional. In addition, the inner packagings must be packed with closures upward. Color may be black or red. Orientation arrows are not required for packages containing biological substances, category B or patient specimens, but they may be used if desired.

A "Cargo Aircraft Only" label is required for shipments that exceed the maximum quantity/weight restrictions specified for passenger aircraft (category A infectious agents by air greater than 50 mL or biological substance, category B greater than 4 liters). A revised version of this label is now required. The old version was authorized for use only until December 31, 2012.
For Category A infectious substances, if an overpack is used, the UN 6.2 certification marking is only required on the outer package of the triple package. The DOT Hazard Class 6 infectious substance diamond, the proper shipping name label with quantity, the shipper’s and receiver’s name and address, the name and telephone number of a person responsible, and the orientation arrow should go on the individual outer packages and the overpack. The DOT Hazard Class 9 diamond, the proper shipping name for dry ice and the weight of the dry ice should be on the overpack. The overpack must also bear a label indicating that the “Inner Packages Comply With Prescribed Specifications.”

For biological substance, category B, if an overpack is used, the overpack must be marked with the work “overpack” and the package markings must be reproduced on the outside of the overpack. The DOT Hazard Class 9 diamond, the proper shipping name for dry ice and the weight of the dry ice should be on the overpack if dry ice is used.

For category A and B infectious substances and human patient specimens, OSHA requires the primary and/or secondary container to be labeled with the biohazard symbol.

If human or animal tissues/specimens are shipped in formaldehyde solutions, they are not likely considered to be infectious, and therefore are not classified as Category A or B Class 6.2 infectious substances. In order to determine the proper shipping name for the formaldehyde solution, it is important to have an SDS for the material being shipped. Full strength formalin is 37% formaldehyde, which should be shipped as “Formaldehyde solutions, flammable, Class 3, UN 1198.” Formaldehyde solutions between 10-15% should be shipped as “Aviation regulated liquid, n.o.s. (formaldehyde) Class 9, UN 3082, III.” Formaldehyde solutions with less than 10% formaldehyde (25% formalin solutions are approximately 9% formaldehyde; 10% neutral buffered formalin is about 3-4% formaldehyde with methanol present) are not classified as a hazardous material for shipment.

**Shipper’s Step Seven: Prepare Appropriate Shipping Papers and Manifest Documentation**

For air shipments of Category A infectious substances, a **Shipper’s Declaration of Dangerous Goods** form is required. The IATA DGR has requirements for color and size of the form that must be used, so black and white copies of this form are not acceptable - an original with the red dotted
The Shipper’s Declaration of Dangerous Goods should be typed or computer templates used. Handwritten declarations will not be accepted by the carrier. See page 15 for information on FedEx software requirements for shipper’s declaration forms.

An example of a completed Shipper’s Declaration of Dangerous Goods is found here.

Note: the Shipper’s Declaration statement at the bottom of the form must read in one of the following formats:

“I hereby certify that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled, and in proper condition for carriage by air according to applicable national governmental regulations. I declare that all of the applicable air transport requirements have been met.”

or

“I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.”
met.”

or

“This is to certify that the above-name materials are properly classified, packaged, marked and labeled, and are in proper condition for transportation according to applicable regulations of the Department of Transportation. I declare that all of the applicable air transport requirements have been met.”

To complete the Shipper’s Declaration, follow these instructions:

1. In the **Shipper** box: Enter the full name, address, and phone number of the shipper. States may be abbreviated to their two-letter code. The phone number should be for the person responsible for shipment.

2. In the **Consignee** box: Enter the full name, address, and phone number of the recipient. States may be abbreviated to their two-letter code. Do not use the University P.O. Box as the address. Use the appropriate street address. The phone number should be for the person responsible for shipment.

3. In the **Air Waybill No.** box: Enter the air waybill number. This may be completed or amended by the shipper, forwarder or carrier. Enter the page number and number of pages (i.e., page 1 of 1).

4. In the **Transport Details** box: Mark out either the “Passenger or Cargo Aircraft” or “Cargo Aircraft Only” box, depending on the quantity you are sending. Remember that when shipping an infectious substance or diagnostic specimen by passenger airline or the United States Postal Service, the total amount in any triple package that can be transported cannot exceed 50 mL or 50 grams. Any quantity over that must be identified as “Cargo Aircraft Only.”

5. Leave the **Airport of Departure** and **Airport of Destination** boxes blank (they may be completed by the carrier) or enter the full name of the airport or city of departure and the full name of the airport or city of destination.

6. In the **Shipment Type** box: Mark out the “Radioactive” box. This manual only describes procedures for non-radioactive shipments. If you are shipping radioactive materials, contact the Radiation Safety Office for assistance.
7. In the **Nature and Quantity of Dangerous Goods** box:

- Fill in the **UN Number**.
- Fill in the **proper shipping name** and put the technical name in parenthesis. The technical name must be spelled out (for example, “HIV” is not acceptable).
- Fill in the **Class and Division number**.
- Fill in the **Packing Group number**, if applicable (note, there is no longer a packing group number for dry ice).
- Fill in the **Subsidiary Risk(s)**, if applicable.

8. In the **Quantity and Type of Packing** box: Provide the net quantity or weight of each type of material. In the case of infectious substances packaged with dry ice in the same outer package, enter the words “All packed in one fiberboard box”. When an overpack is used, the words, “overpack used” must be entered immediately after the entry relating to the packages within the overpack.

9. In the **Packing Instruction** box: Enter the IATA packing instruction number(s) used.

10. In the **Authorization** box: Leave this box blank unless the shipment is being transported under any governmental permits (CDC import permits USDA/APHIS permits, etc.), in which case, list them in the Authorization column and ensure a copy of the authorization, permit, etc., is attached.
11. In the **Additional Handling Information** box: Enter a 24-hour emergency response number. This telephone number must be the number of the person offering the hazardous material for transportation or the number of an agency or organization capable of, and accepting responsibility for, providing detailed information concerning the hazardous material. This number **MUST** be able to be answered by a person knowledgeable of the shipment during the entire time of the shipment period, and should not be the recipient. If not the telephone number of the person offering the material for shipment, for OUHSC Oklahoma City personnel, this number can be 1-405-271-4911 which is the OU Police Department number. **HOWEVER**, if you use the OU Police number you must contact OU Police in advance and tell the dispatcher who you are, what you are shipping, that you have put the OU Police Department phone number on the package, provide a copy of the shipping paper and the emergency response information (see below) to the Communications Specialist (dispatcher), and instruct the dispatcher to provide the emergency response information directly to any inquiries regarding the shipment. You should provide contact information on how to reach you at any time during the shipment period should something occur, but the dispatcher must be instructed to contact you on another line and to not disconnect any emergency call received regarding the shipment.

**NOTE:** Be cautious using shipping papers supplied by vendors that are pre-printed with an emergency response telephone number. As you can see above, this number must be monitored at all times by a person who has knowledge of that particular shipment. Using the receiving organization’s emergency response number can put you at risk if the person answering the phone is not knowledgeable about that shipment. Also, do not automatically assume that putting CHEMTREC’s toll-free number is acceptable. At this point, the University does not have arrangements with CHEMTREC to act as our emergency response telephone number.

12. The signatory box must be **legibly** signed by the person preparing the shipment.

Several copies of the declaration form must be completed and signed. For example, Federal Express requires three copies to be presented with the shipment. At least one signed copy will be retained by the accepting carrier and one is to be forwarded with the shipment to its destination. **One additional copy (this may be an electronic image) must be retained by the shipper for at least two years after the shipment has been accepted by the carrier, and must make this document available to Federal or State inspectors upon request.** Each shipping paper copy must include the date of acceptance by the initial carrier.

**Emergency response information must be provided either on the shipping paper or in a document attached to the shipping paper for any shipment of category A infectious substances.** If you use a document attached to the shipping paper, that document must include both a basic description and technical name of the hazardous material and emergency response information. Safety Data Sheets (SDSs) will suffice for chemical hazards. Some Pathogen Safety Data Sheets for infectious substances are available at [http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php](http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php). Alternatively, the DOT Emergency Response Guide number 158 may be used (see [https://www.ouhsc.edu/ehso/training/erg158.pdf](https://www.ouhsc.edu/ehso/training/erg158.pdf)).

For best practice, make three copies of the applicable SDS or other document which provides sufficient emergency response information. Attach one copy to the shipping paper, keep one copy with you at all times during the shipment process, and provide one copy to the OU Police Department if it is listed as the emergency telephone number.

A shipper’s declaration is not needed for shipping Biological substances, Category B or patient specimens by air, even when shipping them on dry ice, as a shipper’s declaration is not needed if dry ice is the only dangerous good being sent. Instead, the air waybills used by most carriers will have a place to indicate that dry ice is being shipped. In addition, the “Nature and Quantity of Goods” box on the air waybill should show the text “Biological substance, category B” and UN 3373. When shipping Biological substances, Category B by air, the name, address, and telephone number of a responsible person must be provided on the air waybill or on the package, so it is
probably best to be sure to put this information on both.

When transporting Category A or B infectious substances or patient specimens by ground, there is no required form which must be used other than carrier-specific documents.
Shipping Summaries

CATEGORY A INFECTIOUS SUBSTANCE BY AIR, NO DRY ICE - IATA PI 620

1. Identify the materials properly (determine whether UN2900 or 2814, identify infectious agent name).

2. Obtain proper triple packaging.
   a. Inner watertight container
   b. Secondary watertight container
   c. UN approved outer container with markings 4G/UN Class 6.2

3. Assemble the package.
   a. Inner watertight, glass, metal, or plastic container, with heat seal, skirted stopper, or metal crimp seal must be used. If screw caps are used, they must be secured by positive means, such as with adhesive tape.
   b. Place inner sealed container(s) in secondary watertight container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage. **NOTE: The primary and/or secondary container should be labeled with the biohazard symbol.**
   c. Place absorbent material between the inner and secondary container.
   d. Place itemized list of contents between the secondary packaging and the outer UN 6.2 packaging.

4. Mark the shipping container:
   a. DOT 6.2 label
   b. Orientation arrows (on both ends)
   c. Proper shipping name [Infectious substance, affecting humans or animals (no technical name)] and UN number (UN 2900 or 2814)
   d. Names of sender and recipient and their phone numbers
   e. Cargo Aircraft Only label - if you ship more than 50 mL or 50 grams

5. Complete the shipping papers and attach emergency response information. Make the appropriate number of copies for the carrier, one copy for shipper retention, and one copy to the OU Police Department if it is listed as 24-hour emergency response number.
Two completed and signed copies of this Declaration must be handed to the operator.

**TRANSPORT DETAILS**

<table>
<thead>
<tr>
<th>Airport of Departure</th>
<th>Airport of Destination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oklahoma City, OK</td>
<td>Omaha, NE</td>
</tr>
</tbody>
</table>

**WARNING**

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

**SHIPPING PAPER, CATEGORY A INFECTIONOUS SUBSTANCE BY AIR, NO DRY ICE - IATA PI 620**

### NATURE AND QUANTITY OF DANGEROUS GOODS

<table>
<thead>
<tr>
<th>UN or ID No.</th>
<th>Proper Shipping Name</th>
<th>Class or Division (Subdivision)</th>
<th>Packing Group</th>
<th>Quantity and Type of Packaging</th>
<th>Packing Inst.</th>
<th>Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 2900</td>
<td>Infectious Substances, Affecting Animals (Goatpox Virus)</td>
<td>6.2</td>
<td>One fiberboard box x one liter</td>
<td>620</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Additional Handling Information**

**Emergency Telephone Number**

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

**Name/Title of Signatory:** Tyloyd-Mari, RN  
**Place and Date:** Oklahoma City, OK 12 OCT 99  
**Signature:** [Signature]

**FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.**
CATEGORY A INFECTIOUS SUBSTANCE BY AIR, WITH DRY ICE, NO OVERPACK - IATA PI 620, 954

1. Identify the materials properly (determine whether UN2900 or 2814, identify infectious agent name.)

2. Obtain proper triple packaging.
   a. Inner watertight container
   b. Secondary watertight container
   c. UN approved outer container with markings 4G/UN Class 6.2
   d. The outer packaging must allow the escape of carbon dioxide gas

3. Assemble the package.
   a. Inner watertight, glass, metal, or plastic container, with heat seal, skirted stopper, or metal crimp seal must be used. If screw caps are used, they must be secured by positive means, such as with adhesive tape.
   b. Place inner sealed container(s) in secondary watertight container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage. NOTE: The primary and/or secondary container should be labeled with the biohazard symbol.
   c. Place absorbent material between the inner and secondary container.
   d. Place itemized list of contents between the secondary packaging and the outer packaging.
   e. Place dry ice between secondary packaging and outer packaging.
   f. Outer UN 6.2 container holds the secondary container and dry ice.
   g. Items inside must be packed so that they will not shift when dry ice dissipates.

4. Mark the UN 6.2 shipping container:
   a. DOT Hazard Class 6.2 label and DOT Hazard Class 9 label
   b. Orientation arrows (on both ends)
   c. Proper shipping name and UN number for both the infectious agent and carbon dioxide, and quantity of carbon dioxide
   d. Names of sender and recipient and their phone numbers
   e. Cargo Aircraft Only label - if you ship more than 50 mL or 50 grams
5. Complete the shipping papers and attach emergency response information. Make the appropriate number of copies for the carrier, one copy for shipper retention, and one copy to OU Police Department if it is listed as 24-hour emergency response number.
SHIPPING PAPERS, CATEGORY A INFECTIOUS SUBSTANCE BY AIR, WITH DRY ICE, NO OVERPACK - IATA PI 620, 954

<table>
<thead>
<tr>
<th>UN or ID No</th>
<th>Proper Shipping Name</th>
<th>Class or Division (Subclass)</th>
<th>Packaging Group</th>
<th>Quantity and type of packaging</th>
<th>Packing Inst.</th>
<th>Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN2814</td>
<td>Infectious Substances, Affecting Humans (Monkey Pox Virus)</td>
<td>6.2</td>
<td></td>
<td>30 g</td>
<td>620</td>
<td></td>
</tr>
<tr>
<td>UN1845</td>
<td>Dry Ice</td>
<td>9</td>
<td></td>
<td>4 kgs</td>
<td>954</td>
<td></td>
</tr>
</tbody>
</table>

All packed in one fiberboard box

Additional Handling Information

Emergency Telephone Number

(ER Phone # & Contact or Contract #)

Hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory: Anna Thracks, Lab Mgr.
Place and Date: New York City 1 JAN 05
Signature (and witness above): Anna Thracks

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.
1. Identify the materials properly (determine whether UN2900 or 2814, identify infectious agent.)

2. Obtain proper triple packaging and the outer overpack shipping container.
   a. Inner watertight container
   b. Secondary watertight container
   c. UN 6.2 approved outer container with markings 4G/UN Class 6.2
   d. Overpack need not be UN 6.2 approved, but must allow the escape of carbon dioxide gas

3. Assemble the package.
   a. Inner watertight, glass, metal, or plastic container, with heat seal, skirted stopper, or metal crimp seal must be used. If screw caps are used, they must be secured by positive means, such as with adhesive tape.
   b. Place inner sealed container(s) in secondary watertight container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage. **NOTE: The primary and/or secondary container should be labeled with the biohazard symbol.**
   c. Place absorbent material between the inner and secondary container.
   d. Place itemized list of contents between the secondary packaging and the outer UN 6.2 container.
   e. Place UN 6.2 containers in overpack.
   f. Place dry ice between UN 6.2 containers and overpack
   g. Items inside must be packed so that they will not shift when dry ice dissipates.

4. Mark the UN 6.2 outer containers:
   a. DOT Hazard Class 6.2 label
   b. Orientation arrows (on both ends)
   c. Proper shipping name and UN number for the infectious agent
   d. Names of sender and recipient and their phone numbers

5. Mark the overpack (see next page):
   a. DOT Hazard Class 6.2 label
   b. DOT Hazard Class 9 label
   c. Orientation arrows (on both ends)
   d. Proper shipping name and UN number for both the infectious agent and carbon dioxide, and quantity of carbon dioxide
   e. Names of sender and recipient and their phone numbers
   f. Cargo Aircraft Only label - if you ship more than 50 mL or 50 grams
   g. “Inner packages comply with prescribed specifications”
Complete the shipping papers and attach emergency response information. Make the appropriate number of copies for the carrier, one copy for shipper retention, and one copy to the OU Police Department if it is listed as 24-hour emergency response number. (see example, next page).
SHIPPING PAPERS, INFECTIOUS SUBSTANCE/CATEGORY A BY AIR, WITH DRY ICE, OVERPACK - IATA PI 620, 954

**SHIPPER’S DECLARATION FOR DANGEROUS GOODS**

*Proper Shipping Name: Infectious substances, affecting humans (Ebola virus)*

<table>
<thead>
<tr>
<th>UN No</th>
<th>Description</th>
<th>Quantity</th>
<th>Packing Qty</th>
<th>Packing Inst.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2814</td>
<td>Infectious substances, affecting humans (Ebola virus)</td>
<td>6.2</td>
<td>10 fibreboard boxes x 50 ml each</td>
<td>620</td>
</tr>
<tr>
<td>1846</td>
<td>Carbon dioxide, solid (Dry ice)</td>
<td>9</td>
<td>4 kgs</td>
<td>954</td>
</tr>
</tbody>
</table>

**WARNING**

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

**Additional Handling Information**

See attached MSDS

Emergency Telephone Number: (405)271-4911

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled as required, and are in all respects in proper condition for transport according to applicable international and national Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory: Ann Threaks, Lab Mgr.
Place and Date: New York City, March 15, 2011
Signature: [Signature]

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT. THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.
1. Obtain proper triple packaging
   a. Leak-proof primary receptacle
   b. Leak-proof secondary package
   c. The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) in the range of -40°C to 55°C (-40°F to 130°F).
   d. Outer shipping container - does not need to be UN 6.2 approved, but needs to have proof of capability of meeting the drop test requirement.

2. Assemble the package
   a. Place inner sealed container(s) in secondary leak-proof container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage. **NOTE: The primary and/or secondary container should be labeled with the biohazard symbol.**
   b. Place absorbent material between the inner and secondary container.
   c. Place itemized list of contents between the secondary packaging and the outer container.

3. Mark the outer shipping container:
   a. Names, addresses, telephone number for both shipper (responsible person) and recipient.
   b. “Biological substance, category B”
   c. UN 3373 diamond
   d. Orientation arrows (on both ends) (recommended)
   e. Cargo Aircraft Only label - if shipping more than 4 liters

4. Documentation
   a. Shipper’s Declaration for Dangerous Goods is not required.
   b. The “Nature and Quantity of Goods” box on the air waybill should show the text “Biological substance, category B” and UN 3373.
   c. Put name, address, and telephone number of responsible person on air waybill.
1. Obtain proper triple packaging
   a. Leak-proof primary receptacle
   b. Leak-proof secondary package
   c. The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).
   d. Outer shipping container - does not need to be UN 6.2 approved, but needs to have proof of capability of meeting the drop test requirement.
   e. The outer packaging must allow the escape of carbon dioxide gas.

2. Assemble the package
   a. Place inner sealed container(s) in secondary leak-proof container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage. **NOTE: The primary and/or secondary container should be labeled with the biohazard symbol.**
   b. Place absorbent material between the inner and secondary container.
   c. Place itemized list of contents between the secondary packaging and the outer container.
   d. Place dry ice between secondary packaging and outer packaging.
   e. Outer container holds the secondary container and dry ice.
   f. Items inside must be packed so that they will not shift when dry ice dissipates.

3. Mark the outer shipping container:
   a. Names, addresses, telephone number for both shipper and recipient.
   b. “Biological substance, category B”
   c. UN 3373 diamond
   d. “Carbon dioxide, solid, (Dry Ice) UN 1845” and the quantity
   e. DOT Hazard Class 9 label
   f. Orientation arrows (on both ends) (recommended)
   g. Cargo Aircraft Only label - if shipping more than 4 liters
4. Documentation

   a. Shipper's Declaration for Dangerous Goods is not required.
   b. Put name, address, and telephone number of responsible person on air waybill and that dry ice was used (the air waybills used by most carriers will have a place to indicate that dry ice is being shipped)
PATIENT SPECIMEN, BY AIR, NO DRY ICE

1. Obtain proper triple packaging
   a. Leak-proof primary receptacle
   b. Leak-proof secondary package
   c. Outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm.

2. Assemble the package
   a. Place inner sealed container(s) in secondary leak-proof container. Ensure that inner containers are properly wrapped or cushioned to prevent breakage.
   b. Place absorbent material between the inner and secondary container. **NOTE: If specimen is an unfixed human specimen such as blood, tissue, or other potentially infectious material, the primary and/or secondary container should be labeled with the biohazard symbol.**

3. Mark the outer shipping container (see below):
   a. Names and addresses for both shipper and recipient.
   b. “Exempt human specimen” or “Exempt animal specimen”, as appropriate
   c. Orientation arrows (on both ends) (recommended)

![Exempt human specimen]

4. Documentation
   a. Shipper’s Declaration for Dangerous Goods is not required.
NON-INFECTIONOUS BIOLOGICAL MATERIALS (SUCH AS DNA) BY AIR ON DRY ICE - IATA PI 954

1. Obtain proper triple packaging
   a. Inner and outer packages must be of good quality. Dry ice does not require specification packaging but the general provisions described below must be observed.
   b. For liquids in inner packages, closures (i.e. caps) must be held secure by positive means such as tape. Expansion of liquids must be considered due to temperature and elevation changes. Thus, containers of liquids must have sufficient headspace to allow for expansion.
   c. The dry ice must be in outer packaging designed and constructed to permit the release of carbon dioxide gas that forms, preventing the build-up of pressure that could rupture the packaging.
   d. Inner packaging must be packed, secured, or cushioned to prevent breakage or leakage.
   e. Absorbent material is not required.
   f. Do not use plastics that can be rendered brittle or permeable by the temperature of dry ice. This problem can be avoided by using commercially available packages intended to contain dry ice.

2. Assemble the package
   a. Place dry ice between inner packaging and outer packaging.
   b. Items inside must be packed so that they will not shift when dry ice dissipates.

3. Mark the outer shipping container
   a. Names, addresses, telephone number for both shipper and recipient.
   b. “Carbon dioxide, solid, (Dry Ice) UN 1845" and the quantity
   c. DOT Hazard Class 9 label
   d. Orientation arrows not required

4. Documentation
   a. The airbill (also referred to as the air waybill) must include the statement “Dry Ice, Class 9, UN1845, number of packages, ___ net weight in kilograms”. FedEx has a check box in section 6 of their airbill to satisfy this requirement.
>10% FORMALDEHYDE BY AIR - IATA PI 906

1. Identify and classify the material. Determine the final concentration of formaldehyde. If between 10-24.9%, follow these instructions.

2. Obtain proper triple packaging

   a. Leak-proof primary receptacle
   b. Leak-proof secondary package
   c. The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).
   d. Outer shipping container - does not need to be UN 6.2 approved, but needs to have proof of capability of meeting the drop test requirement.

3. Assemble the package

   a. Place inner sealed container(s) in secondary leak-proof container. Ensure that inner containers are properly wrapped/cushioned to prevent breakage.
   b. Place absorbent material between the inner and secondary container.
   c. Place itemized list of contents between the secondary packaging and the outer container.

4. Mark the outer shipping container:

   a. Names, addresses, telephone number for both shipper and recipient
   b. “Aviation regulated liquid, n.o.s. (formaldehyde)” UN3334 and quantity
   c. DOT Hazard Class 9 label
   d. Orientation arrows (on both ends)

5. Complete the shipping papers and attach an SDS that contains emergency response information. Make the appropriate number of copies for the carrier, one copy for shipper retention, and one copy to the OU Police Department if it is listed as 24-hour emergency response number.
Procedures For Receiving Packages

Personnel who receive packages should examine them to determine if damage has occurred and should be knowledgeable about the hazardous nature of the contents. Additional precautions may be necessary if there is any reason to suspect that the material was not packaged, labeled or documented appropriately.

WHAT TO DO IF YOU RECEIVE A DAMAGED PACKAGE

**Category A Infectious Substance/External or Internal Breakage or Leakage**

1. If there is obvious visible damage or liquid or stains are visible on the outside of the package, if at all possible, DO NOT ACCEPT THE PACKAGE.

2. If the package has already been accepted:
   a. Call the Emergency Response Telephone Number listed on the Shipping Paper first for emergency information.
   b. Call the National Response Center at 1-800-424-8802 OR the CDC at 1-800-232-0124 “as soon as practicable but no later than 12 hours after the occurrence” (that doesn’t mean you can wait for 12 hours, it means as soon as you can).
   c. Notify the person who packed or presented the package for shipment and the carrier.
   d. Notify the EHSO (Oklahoma City 405/271-3000, Tulsa 918/660-3878, Norman 405/325-5147).


4. Obtain the identity of the substance involved.

5. Avoid handling the package or keep handling to a minimum. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

6. Inspect adjacent packages for contamination and put aside any that may have been contaminated.

7. Cover damaged package or spilled material with damp towel or rag and keep wet with liquid bleach or other disinfectant.

8. Do not clean up or dispose except under supervision of someone knowledgeable about the hazards associated with the material, and only through following departmental standard operating procedures specific to that material.

9. **New:** A written Hazardous Materials Incident Report on Form DOT F 5800 (see www.phmsa.dot.gov/hazmat/incident-report) must be filed within 30 days of discovery of the incident. Do not submit this form directly - work with the EHSO prior to submitting this form.

**Category B/Patient Specimen External or Internal Breakage or Leakage**

1. If there is obvious visible damage or liquid or stains are visible on the outside of the package, if at all possible, DO NOT ACCEPT THE PACKAGE.

2. If the package has already been accepted, notify the person who packed and presented for shipment and the carrier.

4. Avoid handling the package or keep handling to a minimum. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

5. Cover damaged package or spilled material with damp towel or rag and keep wet with liquid bleach or other disinfectant.

6. Do not clean up or dispose except under supervision of someone knowledgeable about the hazards associated with the material, and only through following spill cleanup procedures found in the OUHSC/OU-Tulsa Laboratory Safety Manual or OUHSC/OU-Tulsa Infectious Diseases Policy/OU Bloodborne Pathogen Exposure Control Plan.

Formaldehyde

1. Notify the person who packed and presented for shipment.

2. Keep unauthorized persons away.

3. Avoid handling the package or keep handling to a minimum. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

4. Using a chemical spill kit, and while wearing protective equipment such as gloves, eye protection, and shoe covers, cover damaged package or spilled material with absorbant.

5. Follow the procedures in the spill kit.

6. Contact the EHSO for disposal of clean-up material.

WHAT TO DO IF YOU HAVE BEEN EXPOSED (CONTACT WITH CONTAMINATED MATERIAL)

1. Notify your supervisor. Depending on the agent, you may consider calling the OU Police Department (911 from a campus phone or 405/271-4911 at OUHSC) or 911 (all other locations).

2. In case of contact with the substance, immediately flush the skin or eyes with running water for at least 20 minutes.

3. Remove and isolate contaminated clothing and shoes.

4. If exposed to diagnostic specimens only, treat the exposure as a bloodborne pathogen exposure and report to Employee Health or Goddard as soon as possible.

5. If exposed to an infectious agent, ensure that all response and medical personnel are aware of the material(s) involved, and take precautions to protect themselves if necessary. Proceed for medical evaluation/treatment as soon as possible.

List of Suppliers of UN/POP 6.2 Packaging

This list is provided solely for assistance to shippers for locating proper packaging. The list is not intended to be an endorsement of the companies listed. While the EHSO has made every effort to provide accurate information, it takes no responsibility for any errors or omissions.

Action Pak, Inc.  
Bristol, PA  
(800) 755-9764  
http://www.actionpakinc.com

AcuTemp  
7610 McEwen Road  
Dayton, OH 45459  
(937) 312-0114  
http://www.acutemp.com

Air Sea Atlanta, Inc.  
1234 Logan Circle  
Atlanta, GA 30318  
(404) 351-8600  
http://www.airseaatlanta.com/62pkg.htm

Air Sea Containers, Inc.  
2749 NW 82nd Ave.  
Miami, FL 33122  
(305) 599-9123
<table>
<thead>
<tr>
<th>Company</th>
<th>Address</th>
<th>Phone</th>
<th>Website</th>
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<tbody>
<tr>
<td>All-Pak, Inc.</td>
<td>Bridgeville, PA</td>
<td>(412) 257-3000</td>
<td><a href="http://www.all-pak.com">http://www.all-pak.com</a></td>
</tr>
<tr>
<td>Cargo Pak Corporation</td>
<td></td>
<td>(800) 266-0652</td>
<td><a href="http://www.cargopak.com">http://www.cargopak.com</a></td>
</tr>
<tr>
<td>Casing Corporation</td>
<td></td>
<td>(800) 358-6866</td>
<td><a href="http://www.casingcorp.com">http://www.casingcorp.com</a></td>
</tr>
<tr>
<td>DG Supplies, Inc</td>
<td>PO Box 400, Dayton, NJ 08810</td>
<td>(800)347-7879</td>
<td><a href="http://dgsupplies.com/">http://dgsupplies.com/</a></td>
</tr>
<tr>
<td>EXAKT-PAK</td>
<td>7002 N. Broadway Extension, Oklahoma City, OK 73116-9066</td>
<td>(405) 848-5800, (800) 866-7172</td>
<td><a href="http://www.exaktpak.com">http://www.exaktpak.com</a></td>
</tr>
<tr>
<td>Federal Industries Corporation</td>
<td>2550 Niagara Lane, PO Box 47099, Plymouth, MN 55447</td>
<td>(800) 523-5093</td>
<td><a href="http://www.chem-tran.com">http://www.chem-tran.com</a></td>
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<tr>
<td>HAZMATPAC, INC.</td>
<td>5301 Polk Street, Bldg 18, Houston, TX 77023</td>
<td>(800) 923-9123</td>
<td><a href="http://www.hazmatpac.com">http://www.hazmatpac.com</a></td>
</tr>
<tr>
<td>Inmark, Inc.</td>
<td>220 Fisk Drive, SW, Atlanta, GA 30336-0309</td>
<td>(800) 646-6275</td>
<td><a href="http://www.inmarkinc.com">http://www.inmarkinc.com</a></td>
</tr>
<tr>
<td>Labelmaster</td>
<td>5724 N. Pulaski Road, Chicago, IL 60646-6797</td>
<td>(800) 621-5808</td>
<td><a href="http://www.labelmaster.com">http://www.labelmaster.com</a></td>
</tr>
<tr>
<td>O. Berk International</td>
<td>860 Springfield Road South, Union, New Jersey 07083</td>
<td>(800) 577-7624, <a href="http://www.aluminumbottles.com/unmail.htm">http://www.aluminumbottles.com/unmail.htm</a></td>
<td></td>
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<tr>
<td>Polyfoam Packers Corp.</td>
<td>2320 Foster Avenue, Wheeling, IL 60090-6572</td>
<td>(888) 765-9362</td>
<td><a href="http://www.polyfoam.com">http://www.polyfoam.com</a></td>
</tr>
<tr>
<td>QorPak</td>
<td>Corporate One West, Bridgeville, PA 15017</td>
<td>(800) 922-7558</td>
<td><a href="http://www.qorpak.com/index.htm">http://www.qorpak.com/index.htm</a></td>
</tr>
<tr>
<td>Saf-T-Pak</td>
<td>#101 17872-106 Avenue, Edmonton, AB Canada</td>
<td>(403) 486-0211, (800) 814-7484</td>
<td><a href="http://www.saftpak.com">http://www.saftpak.com</a></td>
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